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Examining the Effect of a Medication Synchronization or an Education Program on Health Outcomes of Hypertensive Patients in a Community Pharmacy Setting

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Abstract

***Objective**: To examine the effect of a medication synchronization or education program on hypertensive health outcomes.*
***Methods**: This study used a design of randomized controlled trial lasting four months taking place within a family-owned community pharmacy chain in a U.S. Midwestern state. A total of 302 hypertensive patients were randomized into 3 study groups – control, medication synchronization, and education. Interventions included management of medication refills through a medication synchronization program for the medication synchronization group, and monthly hypertension (HTN) education for the education group. Outcome measures included systolic blood pressure (SBP), diastolic blood pressure (DBP), percentage of patients at blood pressure (BP) goal, self-rated change in medication adherence, and patients' HTN knowledge. **Results**: All groups had significant decline of SBP from baseline; however the final analysis showed no significant SBP differences among study groups. The proportion of patients achieving BP goals in both the control (p=0.005) and education (p=0.019) groups increased at Month 4. Changes in self-reported adherence were not significant for any groups. All groups showed positive changes on HTN knowledge questions with the education group showing the greatest change. **Conclusion**: Compared to the control group, there was no difference in the primary outcomes. However, this study demonstrated that educational materials written at an appropriate level and presented by community pharmacists to patients may have been associated with an increase in HTN knowledge and a significant increase in the proportion of patients achieving their BP goal. These educational interventions had a greater impact on helping patients achieve their blood pressure goals than medication synchronization. This may indicate that further intervention is needed to impact adherence aside from ensuring that patients have their medication on hand. Taking the time to educate patients about hypertension led to self-reported positive change with being more careful about taking medications and with not forgetting to take medications when they felt better.*

Introduction

In 2010, 60 million American adults were diagnosed with hypertension (HTN),[1] and the National Heart, Lung, and Blood Institute projected that HTN would cost the U.S. healthcare system over $74 billion (USD) annually.[2] Between 2000 and 2010, the population aged 65 years and over increased at a faster rate than the total U.S. population (15.1% versus 9.7%).[3] Sixty percent of U.S. population between the ages of 60 and 69, 70% between 70 and 79, and 73% 80 years or older had HTN.[2]

Furthermore, medication non-adherence costs the U.S. healthcare system $290 billion annually, and patients with chronic disease are more likely to be non-adherent.[4] Studies have shown that over half of patients being treated for hypertension discontinue therapy within a year of diagnosis, and only half remaining on therapy are >80% adherent to antihypertensive medications.[5,6] Nonadherence is proposed

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to be the most common cause of suboptimal response to antihypertensive therapy.[7] Compounding the issue is a low health literacy rate. According to the U.S. Department of Health and Human Services, over 77 million American adults have basic or below basic health literacy.[8] Low health literacy causes a great deal of miscommunication between healthcare professionals and their patients, and non-adherence leads to poor health outcomes and increased medical costs.[4] The primary care physician population in the U.S. is dwindling, and the number of medical students going into primary care has dropped by over 50% within the past decade.[9] An aging patient population coupled with declining numbers of primary care physicians may limit access to health care for many patients.

The accessibility of community pharmacists puts them in a unique position to help fill the gap in primary healthcare. According to the National Association of Chain Drug Stores, 92% of Americans live within five miles of a community pharmacy.[9] Additionally, the average patient who fills at least 6 prescriptions over a 12 month period, visits his/her pharmacy weekly compared with visiting his/her primary care physician every two and a half months.[9] Moreover, a 2013 Gallup poll cited pharmacists as the second most honest and ethical profession.[10] This level of trust and access places community pharmacists in a position to bridge the gap in care and provide quality, outcomes-based interventions to their patients.

The impact of community pharmacist interventions on health outcomes of HTN has been demonstrated as well. A systematic review and meta-analysis in pharmacists' HTN management reveals that medication management and education about HTN are the most common interventions.[11] Systolic blood pressure (SBP) was found "definitely-sensitive" to pharmacists' interventions, which suggests the impact of pharmacists' interventions on SBP are clinically important and statistically significant. Another systematic review and meta-analysis indicates education about HTN medications by nurses or pharmacists reduces blood pressure (BP).[12] Using a cluster randomized, controlled clinical trial, Carter et al. reported that a physician-pharmacist collaborative intervention achieved better BP control.[13] In addition, Svarstad et al. used a cluster randomized trial to examine community pharmacists' intervention of education and adherence monitoring for black hypertensive patients.[14] They found that the intervention had a positive impact on improving refill adherence and lowering SBP.

A 2008 Cochrane collaboration reviewed studies that aimed to impact change in medication adherence.[15] Interventions for hypertensive patients included complicated, time intensive intervention, simplifying regimens, phone reminders and education, home BP monitoring and use of blister packaging. None of the studies cited use of medication synchronization as an intervention. Medication synchronization involves pharmacists working with patients to coordinate chronic refill medications to come due on a single day of the month.[16] A study by Holdford and Inocencio demonstrated that the use of an appointment-based medication synchronization program in community pharmacy was associated with improved adherence and reduced likelihood of nonpersistence.[16]

Objective

The objective of this study was to examine the effect of a medication synchronization program or an education program on hypertensive patients' health outcomes. These outcomes included SBP, diastolic blood pressure (DBP), proportion of patients at BP goal, change in self-rated medication adherence, and patients' knowledge of HTN-related topics. The authors hypothesized education and medication synchronization interventions would produce significant SBP lowering compared to a control group.

Methods

Study Population and Study Design

The study took place at a family-owned, 15 store community pharmacy chain in northwest-central Missouri and was approved by the University of Missouri—Kansas City's Adult Health Sciences Institutional Review Board. Patients were enrolled at six retail locations and randomized by research staff into three groups based on enrollment order: control, medication synchronization, or education. Randomization occurred at the patient level, and within each pharmacy. Patients were given a number based on the order of enrollment and were not blinded to other groups. For example, the first person was assigned to group one (control), second to group two (medication synchronization), third to group three (education), fourth to group one (control), and so on. Study recruitment and follow-up lasted from January 2012-June 2012. Study locations were chosen based upon clinical staffing levels and availability to complete the study in the four-month time frame. The inclusion criteria were: 18 years of age or older, diagnosis of HTN inferred by medication use, prescribed at least one BP medication, and filled two or more prescriptions at the study site. Excluded patients were less than 18 years of age, had limitations to diet or exercise modification, experienced a heart attack or stroke within the six months prior to enrollment, had kidney failure or were on dialysis. Eligible patients received an invitation letter to participate and study participants received an automatic BP monitor for home use upon completing all visits as an incentive for participation.

Study Interventions

All study participants completed a baseline and final questionnaire assessing their adherence to medication and knowledge of HTN. Additionally, all patients received monthly blood pressure measurement, four times in total, to allow for comparisons in clinical data between groups.[17] Two readings were taken at each visit with an automatic BP monitor, HoMedics BP-060 (HoMedics, Inc.; Commerce Township, Michigan). An automatic meter was selected instead of stethoscope and sphygmomanometer to reduce variability between pharmacists taking BP readings. All participating pharmacists were trained by one researcher on appropriate use of this specific meter to ensure fidelity of measurements. Each patient was measured for correct cuff size, and monitored using an adult regular or adult large BP cuff. The readings were obtained one to two minutes apart, after an initial five minute resting period, with feet flat on the floor, and without talking. If the two SBP readings had greater than 6 mmHg difference, a third reading was taken, and the two values closest in range were recorded. Hypertensive patients, or those with comorbidities including diabetes, were assigned a goal of less than 140/90 or 130/80 mmHg, respectively.[18]

Control group patients did not receive additional intervention beyond monthly blood pressure checks assessed on a walk-in basis. Essentially this served as a feedback loop where control patients received feedback about their blood pressure. They were not reminded to come to the pharmacy to refill medications or to have their blood pressure measured. Medication synchronization group patients had all of their maintenance medication fills, including antihypertensive medication(s), synchronized to the one day each month that worked best for them to pick up all of their medications. This is referred to as the Appointment Based Model (ABM).[19] Prior to the appointment day, the patient was then called by a pharmacy staff member to determine if any medication changes occurred since the last month's appointment. This process reduced lapses in treatment by allowing the pharmacy staff to be proactive if a medication was in need of a refill or prior authorization. Additionally, refilling all medications on the same date allowed for monthly reviews of patients' complete current medications. The patient was then notified via phone call, or if preferred via text messaging, when all of the medications were ready to be picked up. BPs were measured for medication synchronization patients monthly upon picking up their medications. Education group patients received a monthly education session covering various topics related to HTN and improving hypertensive health outcomes, were given education materials to take home, and had their knowledge assessed at the visit. Education visits were conducted by a pharmacist and occurred concurrently with the BP measurement, on a walk-in basis. These patients were only asked to complete BP assessments if they were in the pharmacy filling prescriptions. They were not reminded to pick up prescriptions or to come to the pharmacy for BP visits. Education sessions were performed based upon a set of four patient handouts. Pharmacists provided an overview and discussion with each patient about the information contained within one handout during their monthly visit. The handout was then provided to the patient to take home and use as a reference. Handouts were presented within a 10-15 minute timeframe, and allowed comprehensive patient education without adversely affecting pharmacy workflow. Additionally, education patients completed a pre and post-test regarding the education topic to assess baseline knowledge and retention of information presented. Questions asked before and after education sessions were directly related to the monthly education topic presented. The same pharmacist did not perform every education session; however, one researcher trained all participating pharmacists to perform the sessions. The standardized training provided consistency to the education sessions. The handouts were presented in the following order: the basics of BP, lifestyle modification through diet, lifestyle modification through exercise, and the importance of medication adherence. All handout information was derived from the American Heart Association (AHA) and the JNC-7 hypertension guidelines.[18,20] Each topic was written at a fifth grade reading level, and printed in color.

For all study groups, patients' self-reported adherence to medication regimens was measured via the Morisky, Green, and Levine (MGL) Adherence Scale.[21] The MGL is a series of four yes/no questions, scored zero through four, which were incorporated into the baseline and final questionnaires. If patients answered "yes" to any question, they were more likely to be non-adherent.[21] Adherence was measured by a self-rated scale alone because measuring prescription refill history would show perfect adherence within the medication synchronization group due to the nature of the intervention.

Patients' knowledge of topics related to HTN was assessed in the baseline and final questionnaire with a series of five questions related to BP goals, influence of diet and exercise on BP, complications of uncontrolled HTN, and identification of BP medications. The knowledge questions were derived from the AHA website, and correspond with questions asked on pre/post-tests administered during education visits.[20] All education topics and HTN knowledge pre/post-tests were reviewed by clinical staff, non-clinical staff, and lay people for clarity and relevance prior to administration to patients.

Outcomes

The main outcome measures of this study are systolic blood pressure (SBP), diastolic blood pressure (DBP), percentage of patients at blood pressure (BP) goal, self-rated change in medication adherence, and patients' HTN knowledge.

Statistical Analysis

Sample size was estimated by an ANOVA test with a detected change in SBP of 6 mmHg between the education group and the medication synchronization or control group,[22] a SBP standard deviation of 15 mmHg,[22] an alpha of 0.05, and a beta of 20%. A total of 276 patients, or 92 patients per study group, were needed and a sample size of 300 patients, or 100 patients per group was selected. Thus each study location recruited 50 patients. Patients' baseline characteristics were reported using descriptive statistics. One-way ANOVA tests compared continuous variables including patient BP among groups. Chi-square tests compared categorical variables among groups. In addition, for each group, since the data of SBP and DBP were normally distributed (demonstrated by Shapiro-Wilk Test), paired t-tests were performed to compare SBP and DBP at baseline versus Month 4. For each group, evaluation of BP goal, and patients' adherence and knowledge at baseline versus Month 4 was assessed via the McNemar Chi-square test. Statistical analyses were conducted via a "per-protocol" approach (i.e., patients lost to follow up were excluded) and a p-value of <0.05 was considered statistically significant.

Results

Enrollment letters were sent to 6,397 patients and 302 enrolled to participate in the study. Three hundred and two patients were randomized into the three study groups: control, medication synchronization, and education. At the conclusion of the study, 94, 95, and 86 patients in the control group, medication synchronization group, and education group, respectively, completed all study activities. Nine, seven and eleven patients were lost to follow-up in the control, medication synchronization, and education groups respectively. Reasons for loss at follow-up included: patients not willing to complete interventions, patients consistently not showing for visits, and patients entering long term care facilities. Baseline characteristics of study patients are displayed in Table 1. All baseline characteristics were similar among groups. Patients were generally female, 65 years of age, taking at least two BP medications, and had a high school education or above. Of the total study population, 41% were male and 27% were diabetic.

All groups had a significant SBP decline ($p<0.05$) from baseline, however there were no significant monthly SBP differences among study groups (Table 2). Also, the control group produced significant DBP ($p=0.002$) decreases from baseline, but there were no significant differences among study groups at final BP analysis. For the control group and education group, the proportion of patients achieving BP goals increased at Month 4 (Table 3). From the baseline/final questionnaire, there were no significant changes in subject perception of adherence before and after the intervention for any study group (Table 4). The most commonly reported reason for non-adherence was forgetfulness with 50.6% of patients reporting this reason. Control group patients had a positive change on 20% of HTN knowledge questions, while medication synchronization group patients had a positive change on 40%. The education group improved scores on 60% of HTN knowledge questions. Notably, the education group experienced a 27.1% increase in correct identification of appropriate amount of exercise needed for BP lowering ($p<0.001$).

Discussion

Our study evaluated the effect of community pharmacist intervention on SBP and DBP among groups and from baseline, proportion of patients achieving BP goal, and patient perception of medication adherence. In this study all groups produced significant SBP lowering from baseline, however there were no significant SBP differences among study groups. A significant SBP difference between groups may have been seen if only patients with uncontrolled HTN were enrolled in the study. At baseline each study group started out with a substantial proportion of patients already meeting treatment goals: control 49.0%, medication synchronization 41.8%, and education 38.3%. This may have reduced the ability to see improvements across all groups. Had only patients with uncontrolled hypertension been enrolled there would have been more room for impact. However, we felt enabling all patients, even those at goal, to take charge of their health through lifestyle was a worthy cause and reason to include these patients, if interested in participation.

Control group patients had their BPs assessed each month in order to provide feedback to the participants regarding what their blood pressures are and to compare their clinical data to the other groups receiving interventions. It appears this feedback monitoring without additional intervention has impacted their blood pressures in a positive way. This reduction in BP may not have been seen if they had simply been assessed at baseline and/or at the end of the study period. The proportion of patients achieving BP goals significantly increased in the control and education groups after the interventions. Controlling BP to within the goals outlined by current HTN guidelines[18] is integral to prevention of serious target organ damage from uncontrolled HTN.

The absence of change in self-reported adherence scores within study groups suggests it is difficult to change patient adherence by the singular act of synchronizing medications and reminding the patient to pick them up when they are due. There is a need for interventions that focus on motivation and awareness of the importance of taking medication as prescribed in addition to ensuring the patient physically has the medication. With forgetfulness being the most commonly reported reason for non-adherence in this study, it is important for community pharmacists to communicate with patients about barriers to adherence. The proactive nature of the medication synchronization program allows the pharmacy staff to prepare for patient consultations regarding adherence or other underlying health or medication-related issues by knowing when to expect these patients at the pharmacy using the ABM. While providing education on medication regimens, community pharmacists can impact adherence by suggesting additional tools, such as medication planners and alarms, to remind patients to take their medications. Given the need to follow the research protocol and measure BP at pick up times, adherence was not directly discussed with medication synchronization patients; it was only evaluated through the study questionnaire.

Based on answers to HTN knowledge questions, patients in the education group improved on questions regarding the amount of exercise needed to impact BP lowering. Awareness of the appropriate amount of exercise may influence patients to exercise more, and consequently decrease BP. Exercise is an important component to attaining BP control. Within the education group, 60% of knowledge questions on pre/post-tests demonstrated an increase in proportion of patients answering the question correctly after the intervention. This indicates that the educational materials presented to patients may have successfully informed them on various HTN topics.

Limitations

The short four-month duration was a limitation of this study. A longer time period may be necessary to detect significant SBP differences between intervention groups at final analysis. There may have been selection bias in the study where the people who volunteered are likely different from those who did not. This may explain why medication synchronization did not have an impact on BP reduction. The control group may have also experienced compensatory rivalry. Upon knowing the other two groups were receiving an additional intervention, they may have decided to seek out additional intervention on their own or modify their own medication-taking behaviors. Another limitation was subject behavioral factors that could cause elevated blood pressure were not assessed. These factors might include exercise, caffeine intake, stress, and/or nicotine intake within 30 minutes prior to BP measurement. Additionally, although the pharmacists performing the interventions were trained prior to enrollment by a sole researcher, they were not monitored throughout the study to ensure the integrity of design was maintained.

For a self-reported adherence measure, such as the MGL, patients may be more likely to respond with what the health provider would like to hear versus how they actually use medications. Although, completing a paper survey may allow the patient to answer more freely than when answered face to face. Despite limitations, steps were taken to minimize the amount of bias and incidence of error. This included randomization, offering enrollment to all HTN patients at the pharmacy, and estimating sample size based on sufficient power.

Trending results including decreased blood pressure and changes in knowledge are promising, and future studies of longer duration and modified study logistics need to be conducted to examine differences among study groups. Based on the results of this study, a hypertension monitoring fee-for-service program was implemented in all pharmacies within the organization. Additionally, it was determined that the medication synchronization program needed enhancement to include a patient consultation each month when medications were picked up to assess adherence, changes in regimen, or any additional questions or concerns.

Conclusion

All groups had significant SBP lowering from baseline to Month 4, however there were no significant SBP differences among study groups. Medication synchronization did not lead to a significant increase in proportion of patients at BP goal. This may indicate that further intervention is needed to impact adherence aside from ensuring that patients have their medication on hand. There were no significant changes in self-reported medication adherence in any study groups, but the education group reported positive change with being more careful about taking medications and with not forgetting to take medications when they felt better. This study also demonstrated that educational materials written at an appropriate level and presented by community pharmacists to patients may have been associated with an increase in HTN knowledge and a significant increase in the proportion of patients achieving their BP goal.

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Table 1. Baseline characteristics of patients

Characteristics	All Subjects (n=302)	Control (n=103)	Medication synchronization (n=102)	Education (n=97)	P[a]
Age (mean ± SD)[b]	n=288	n=98	n=94	n=96	0.330
Years	65.5 ± 13	66.2 ± 13	63.9 ± 12	66.4 ± 12	
Gender (%)[c]	n=294	n=101	n=99	n=94	0.818
Male	41	36	45	42	
BP medications (average #)[b]	n=282	n=96	n=96	n=90	0.259
Number of medications	2.1	2.1	2.2	1.9	
Time since diagnosis (%)[c]	n=274	n=90	n=96	n=88	0.241
<1 year	4.0	2.2	3.4	6.8	
1-2 years	8.4	7.8	6.3	11.4	
3-10 years	42.7	37.8	43.8	46.6	
>10 years	44.9	52.2	46.9	35.2	
Education (%)[c]	n=278	n=93	n=95	n=90	0.286
No education	1.0	1.1	0	2.2	
Kindergarten through 8th	1.4	2.2	0	2.2	
Some High School	10.1	5.4	16.8	7.7	
High School Graduate	42.1	42.0	45.3	38.9	
Some College	24.8	26.9	23.2	24.4	
College Graduate	14.4	16.1	11.6	15.6	
Post Graduate/Professional	6.1	6.5	3.2	8.9	
Adherence[c,d] (%)					
Have you ever forgotten to take your medication?	n=290	n=98	n=97	n=95	0.972
Yes	53.8	53.1	53.6	54.7	
At times are you not careful about taking your medications?	n=290	n=98	n=97	n=95	0.574
Yes	15.5	17.3	12.4	16.8	
When you feel better, do you sometimes forget to take your medications?	n=289	n=97	n=97	n=95	0.950
Yes	9.0	9.3	8.2	9.5	
At times, if you feel worse when you take your medicine, do you stop taking them?	n=290	n=98	n=97	n=95	0.479
Yes	4.1	5.1	5.2	2.1	

[a] p <0.05 is statistically significant
[b] Evaluated via ANOVA
[c] Evaluated via Chi-Square test
[d] Measures were derived from: Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. Med Care. 1986;24:67-74.
Abbreviations: SD = Standard deviation
n varied due to missing data.

Table 2. Changes in average SBP and DBP between groups and from baseline to final

Visit	All Subjects (n=302)	Control (n=103)	Medication synchronization (n=102)	Education (n=97)	P[c]
SBP[a,b]					
Baseline	138 (n=302)	137 (n=103)	137 (n=102)	139 (n=97)	0.704
Month 2	133 (n=288)	130 (n=96)	134 (n=98)	136 (n=94)	0.108
Month 3	129 (n=276)	130 (n=93)	129 (n=96)	129 (n=87)	0.841
Month 4	130 (n=275)	128 (n=94)	133 (n=95)	129 (n=86)	0.165
Difference between baseline and Month 4 [a,d]	8	9 **(p 0.001)**	4 **(p 0.041)**	10 **(p <0.001)**	
DBP[a,b]					
Baseline	79 (n=302)	79 (n=103)	79 (n=102)	79 (n=97)	0.871
Month 2	77 (n=288)	76 (n=96)	77 (n=98)	77 (n=94)	0.681
Month 3	74 (n=276)	75 (n=93)	75 (n=96)	74 (n=87)	0.822
Month 4	76 (n=275)	76 (n=94)	77 (n=95)	76 (n=86)	0.695
Difference between baseline and Month 4 [a,d]	3	3 **(p 0.002)**	2 (p 0.302)	3 (p 0.083)	

[a] Measured in millimeters of mercury (mmHg)
[b] Evaluated via one-way ANOVA
[c] p<0.05 is statistically significant, and significant p vales were bolded.
[d] Evaluated via paired t-test
Abbreviations used: SBP = systolic blood pressure; DBP = diastolic blood pressure

Table 3. Proportion of subjects achieving blood pressure goals[a]

Group	Baseline at goal (%)	Month 4 at goal[c] (%)	Difference (%)	P[d]
Control (n[b]=96)	49.0	70.8	21.8	**0.005**
Medication synchronization (n[b]=98)	41.8	60.2	18.4	0.185
Education (n[b]=94)	38.3	61.7	23.4	**0.019**

[a] Blood pressure goals: <140/90 mmHg (non-diabetic), <130/80 mmHg (diabetic)
[b] n was determined by including all subjects with at least 2 recorded blood pressure readings
[c] Patients at blood pressure goal at month four that had received at least two measurements: baseline and month four
[d] p<0.05 is statistically significant, and significant p vales were bolded.

Table 4. Change in percentage of patient responses between baseline and Month 4

Questions	Control (n= 85)		Medication synchronization (n= 79)		Education (n=76)	
	Difference (%)	P[c]	Difference (%)	P[c]	Difference (%)	P[c]
Adherence[a,b] Have you ever forgotten to take your medication?	4.7	0.503	1.3	1.000	7.9	0.210
At times are you not careful about taking your medications?	-8.2	0.167	0.0	1.000	-5.4	0.424
When you feel better, do you sometimes forget to take your medications?	1.2	1.000	2.6	0.754	-5.4	0.344
At times, if you feel worse when you take your medicine, do you stop taking them?	1.2	1.000	2.6	0.727	2.7	0.687
Knowledge[b,d] What is your goal blood pressure?	2.4	0.804	2.5	0.791	1.3	1.000
What foods/drinks can cause your blood pressure to go up?	13.8	0.050	19.8	**0.005**	18.5	**0.011**
What problems cannot be caused by high blood pressure?	-3.4	0.678	11.1	0.078	11.1	0.064
Which of these is a blood pressure medication?	19.5	**0.002**	25.9	**0.000**	34.6	**0.000**
How often should you exercise to decrease your blood pressure?	-5.7	0.442	6.2	0.473	27.1	**0.000**

[a] Measures were derived from: Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. Med Care. 1986;24:67-74.
[b] Evaluated via Chi-Square test
[c] p<0.05 is statistically significant, and significant p values were bolded.
[d] Questions derived from The American Heart Association website